

# EXHIBIT 2

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

THE UNITED STATES OF AMERICA, *ex rel.*  
JULIE LONG,

*Plaintiffs,*

v.

JANSSEN BIOTECH, INC.,

*Defendant.*

Civil Action No. 16-CV-12182-FDS

**DEFENDANT JANSSEN BIOTECH, INC.’S AMENDED WRITTEN RESPONSES TO  
RELATOR’S NOVEMBER 4, 2022 30(B)(6) DEPOSITION NOTICE**

Pursuant to the Court’s March 9, 2023 Order, Defendant Janssen Biotech, Inc. (“Janssen” or “Defendant”) provides the following amended objections and responses to Relator’s Notice of Deposition pursuant to Federal Rule of Civil Procedure 30(b)(6) (the “30(b)(6) Notice”), dated November 4, 2022.

**GENERAL OBJECTIONS**

1. Janssen objects to each Topic set forth in the Notice to the extent that it calls for information protected from disclosure by the attorney-client privilege, the protection afforded work product, or any other applicable privilege or protection. As previously stated, Janssen has not asserted and does not intend to assert the advice of counsel defense. For avoidance of doubt, by providing the requested factual information regarding the identities of the individuals who provided privileged legal advice, Janssen is not asserting the advice of counsel defense and has not waived any applicable privilege.

2. Janssen objects to each Topic set forth in the Notice to the extent it is vague and ambiguous, or fails to state with “reasonable particularity the matters for examination” as required by Rule 30(b)(6) of the Federal Rules of Civil Procedure.

3. Janssen objects to each Topic to the extent that it seeks information not relevant to any claim, counterclaim, or defense pled by any party in this action.

4. Janssen objects to each Topic to the extent that it is overly broad and unduly burdensome and not proportional to the needs of the case, and thus exceeds the scope of discoverable matters under Fed. R. Civ. P. 26.

5. Janssen objects to each Topic set forth in the Notice to the extent that it calls for information that is confidential or proprietary to Janssen. To the extent that Janssen provides such information, it will do so pursuant to the terms of the Protective Order entered in this case on March 11, 2021.

6. Janssen objects to each Topic set forth in the Notice to the extent it purports to impose any obligation on Janssen to locate, obtain, and/or provide testimony or documents regarding information not in the possession, custody, or control of Janssen.

7. Janssen objects to each Topic set forth in the Notice to the extent it seeks to impose obligations or requirements on Janssen which are greater than or different from those imposed by the Federal Rules of Civil Procedure and/or any other applicable law, rule, or regulation.

8. Janssen objects to any implications and to any explicit or implicit characterization of facts, events, circumstances, or issues set forth in the Notice. Any response by Janssen is not intended to indicate that Janssen agrees with any implications or any explicit or implicit characterization of facts, events, circumstances, or issues in the Notice, or that such implications or characterizations are relevant to this action.

9. Janssen objects to each Topic set forth in the Notice to the extent it seeks information outside of the scope authorized by the Court. Specifically, Janssen objects to each

Topic to the extent it seeks information outside the scope of the phased discovery authorized by the Court on December 14, 2020, and in subsequent orders by Chief Magistrate Judge Kelley, to the extent it seeks information that is not related to support services provided by Relator during her employment as an ABS at Janssen to the physician practices specifically alleged in the Second Amended Complaint.

10. Janssen's responses are made without waiving or intending to waive in any way (a) any objections as to competency, relevancy, materiality, privilege and/or admissibility, or subject matter thereof, in any subsequent proceeding in this or any other action; (b) the right to object on any ground to the use of these responses, or the subject matter thereof, in any subsequent proceeding in this or any other action; (c) the right to object to a demand for further responses to these or any other discovery involving or related to the subject matter of these topics; and (d) the right to object on any ground to these or any other or future discovery responses.

### **SPECIFIC OBJECTIONS AND RESPONSES**

**TOPIC NO. 1:** The persons (excluding the PRC) that had significant involvement in the development and/or approval of the strategy or plan to provide and/or continue to provide any or all of the IOI Support Services (including the specific IOI Support Service(s) in which each such person had the significant involvement, the approximate date(s) of the significant involvement, the person's last known address and phone number, and, if an individual, the position they held at the time of their significant involvement).

*Relevant time period:* From when the strategy of providing the IOI Support Services was devised until February 19, 2016.

#### **RESPONSE TO TOPIC NO. 1:**

Janssen objects to this Topic to the extent that it is overly broad and unduly burdensome and not proportional to the needs of the case, and thus exceeds the scope of discoverable matters under Federal Rule of Civil Procedure 26.

Janssen further objects to this Topic to the extent it is cumulative and seeks information that is duplicative of what is contained in the documents or written discovery that Janssen has already produced.

Janssen further objects to this Topic on the ground that it is vague, ambiguous, and overbroad and does not describe with reasonable particularity the matters on which examination is requested as required by Fed. R. Civ. P. 30(b)(6). For example, Janssen objects to the Topic's use of the terms "development," "approval," "strategy," "plan," and "significant involvement," as those are not defined terms. "Significant involvement," in particular, is an inherently subjective term, and reasonable minds could differ as to whether a particular person was "significantly" involved in any given activity. This response is based on Janssen's good faith understanding, and it seeks to address Relator's concerns about providing a response that is over-inclusive or under-inclusive.

Further, pursuant to the Court's March 9, 2023 order, Janssen's response will "only be with regard to the services at issue in this case, not all services." *See ECF No. 375 at 18.* Accordingly, Janssen's response to Topic No. 1 will be with respect to the IOI Support Services identified by Relator in response to Janssen's Interrogatory No. 2. *See Relator's 3d Supplemental Objections and Responses to Janssen's Rog. No. 2 (January 27, 2023).*

Although Topic No. 1 requests information through February 16, 2016, Janssen has provided responsive information through February 2020.

Subject to and without waiving the foregoing objections, Janssen responds as follows:

The individuals with significant involvement in the initial strategy to provide educational support to physicians (which began in approximately 1998 when Remicade was first approved) and the development of the initial educational materials related to IOI (the "Practice

Management Program”) were Mike Ziskind, Brian Fitzpatrick, Julie McHugh, and Chris Zalesky.

The development and/or approval of the strategy or plan to provide and/or continue to provide the IOI Support Services identified by Relator in response to Janssen’s Interrogatory No. 2 was a function of certain members of the Site of Care (“SOC”) team. The SOC team was responsible for developing educational materials for use by the Area Business Specialists (“ABS”) with all sites of care for Remicade and Simponi Aria, such as: (1) Rheumatologists, Gastroenterologists, and Dermatologists; and (2) “Alternative Sites of Care,” including Hospital Outpatient Departments and Infusion Therapy Providers, which included Ambulatory Infusion Centers and Home Infusion Providers.

Given the number of functions served by the SOC team, as a general matter, the individuals significantly involved in the development and/or approval of the strategy or plan to provide and/or continue to provide the IOI Support Services were the Product Director and Product Manager responsible for the IOI educational materials used by the ABSs. Generally, either the SOC Product Director or the Product Manager responsible for the IOI educational materials was the individual identified as the “Project Owner” on the PRC forms that have been produced in this matter. Further, as a general matter, Group Product Directors, Directors, and Vice Presidents (as identified on the organizational charts produced in this litigation) were not significantly involved in the development and/or approval of the strategy or plan to provide and/or continue to provide the IOI Support Services, given their broad range of responsibilities.

The SOC team has been housed in different groups of the Immunology Division. Specifically, in 2003, the SOC team was part of the Strategic Customer Relations Group. *See* JANSSEN BIO-042-00000024-37 at JANSSEN BIO-042-00000035. In 2006, the SOC team was

part of the Strategic Business Franchise. *See JANSSEN BIO-042-00000093-103* at 101. In 2007, the SOC team was its own group within the Immunology Division. *See JANSSEN BIO-042-00000104-117* at 112. Between 2008 and the end of 2009, the SOC team was combined with Academic Marketing (the team responsible for marketing related to educational institutions, such as universities). *See JANSSEN BIO-042-00000129*. Between 2010 and 2011, the SOC team was combined with Payer Marketing (the team responsible for marketing related to insurance companies). *JANSSEN BIO-042-00000132; JANSSEN BIO-042-00000125*. In the Fall of 2011, the SOC team was divided between the Rheumatology Group and the Gastroenterology Group. *See JANSSEN BIO-042-00000136*. In 2014, Janssen again reorganized, and the SOC team was placed in the Immunology Inc. Portfolio group.<sup>1</sup> *See JANSSEN BIO-042-00000124*. As of February 2020, the SOC team remained a part of this group.

The following list encompasses the individuals significantly involved in the development and/or approval of the strategy or plan to provide and/or continue to provide the IOI Support Services identified by Relator in response to Janssen's Interrogatory No. 2:

<b>Individual</b>	<b>Title</b>	<b>IOI Support Program(s)</b>
John Arena	Product Manager, Site of Care (May 2009–June 2010); Product Director, Site of Care (July 2010–approx. 2012)	Significantly involved in the SOC strategy and the development of IOI educational materials in use between May 2009 and 2012.  Listed as the Project Owner on relevant PRC forms, including for at least the following IOI Support Services:  Considerations for Proactive Practice Management

---

<sup>1</sup> In 2016, the Immunology Inc. Portfolio Group was renamed "Immunology Portfolio Solutions." *See JANSSEN BIO-042-00000119*. In 2018, the Immunology Portfolio Solutions group was renamed "Immunology Biosimilar and Portfolio Strategy." *See JANSSEN BIO-047-00009633*.

<b>Individual</b>	<b>Title</b>	<b>IOI Support Program(s)</b>
Janice Babia-Ramos	Manager, Health Economics & Reimbursement (Jan. 2003–Jan. 2005); Senior Manager, Site of Care (Feb. 2005–Mar. 2005); Associate Director, Site of Care (Mar. 2005–May 2005)	<p>Significantly involved in the SOC strategy and the development of IOI educational materials, including IOI Support Services, in use between January 2003 and May 2005.</p> <p>Listed as the Project Owner on relevant PRC forms, including for at least the following IOI educational materials:</p> <p><u>Infusion Optimization Modeler (IOM)</u></p>
Darah Biddle	Product Manager, Crohn's Disease (Aug. 2010–May 2012); Product Director, Institutional Marketing (May 2012–Apr. 2014)	<p>Listed as the Project Owner on relevant PRC forms, including for at least the following IOI Support Services:</p> <p><u>Infusion Therapy Services Provided in Converted ASC Space;</u>  <u>IV Therapy: An Important Option for Your Patients (a/k/a Why IV?);</u>  <u>Successful Implementation of a New Infusion Suite for Gastroenterology Practices;</u>  <u>Successful Infusion Suite Management;</u>  <u>Successful Infusion Suite Management for Gastroenterology</u></p>
Michelle Carrigan	Product Director, Channel Marketing (Nov. 2019–Mar. 2022)	Significantly involved in the SOC strategy and the development of IOI educational materials, including IOI Support Services, in use between November 2019 and February 2020.
Lawrence Conley	Product Manager, Site of Care/Institutional Marketing (Feb. 2013–Oct. 2013); Product Manager, Gastroenterology (Nov. 2013–Apr. 2016)	<p>Significantly involved in the SOC strategy and the development of IOI educational materials in use between February 2013 and April 2016.</p> <p>Listed as the Project Owner on relevant PRC forms, including for at least the following IOI Support Services:</p> <p><u>Infusion Optimization Modeler (IOM);</u></p>

<b>Individual</b>	<b>Title</b>	<b>IOI Support Program(s)</b>
		Infusion Services Review (iBiz); IV Therapy: An Important Option for Your Patients (a/k/a Why IV?)
Camille Dorsey	Product Manager, Remicade (April 2012–May 2015); Product Director (Mar. 2015–Nov. 2017)	Listed as the Project Owner on relevant PRC forms, including for at least the following IOI Support Services:  Considerations for Proactive Practice Management; Successful Infusion Suite Management for Gastroenterology
Joseph Donahue	Product Manager, Site of Care (May 2006–June 2007)	Significantly involved in the SOC strategy and the development of IOI educational materials, including IOI Support Services, in use between May 2006 and June 2007.  Listed as the Project Owner on relevant PRC forms, including for at least the following IOI Support Services:  Setting Up In-Office Infusions of Remicade
Maria Finlay	Product Manager, Immunology Marketing (Sept. 2010–Apr. 2013)	Significantly involved in the SOC strategy and the development of IOI educational materials, including IOI Support Services, in use between September 2010 and April 2013.  Listed as the Project Owner on relevant PRC forms, including for at least the following IOI Support Services:  Raising the Infusion Suite Experience (RISE)
Ken Gillmer	Senior Product Manager, Site of Care Marketing (June 2006–Aug. 2007); Associate Director, Site of Care (Aug. 2007–Oct. 2008); Director, Site of Care Marketing (Oct. 2008–Oct. 2010)	Significantly involved in the SOC strategy and the development of IOI educational materials, including IOI Support Services, in use between June 2006 and October 2010.

<b>Individual</b>	<b>Title</b>	<b>IOI Support Program(s)</b>
		<p>Listed as the Project Owner on relevant PRC forms, including for at least the following IOI Support Services:</p> <p>Becoming an Alternative Site of Care; Considerations for Proactive Practice Management; Enhancing Patient Care and Access; Managing Biologics in the Physician Office; Practice Compliance for Remicade; Private Payer Contracting Considerations; Setting Up In-Office Infusions of Remicade</p>
Kendra Heusinkveld	Product Manager, Emerging Stakeholders (Oct. 2015–May 2017)	<p>Significantly involved in the SOC strategy and the development of IOI educational materials, including IOI Support Services, in use between October 2015 and May 2017.</p> <p>Listed as the Project Owner on relevant PRC forms, including for at least the following IOI Support Services:</p> <p>Infusion Services Review (iBiz); Infusion Suite Scheduling &amp; Staffing; Quality of Care in the Infusion Suite; In-Office Infusion Drug Procurement Models; Inventory and Supply Management; Billing and Coding for Infusions; ICD-10; Clinical Protocols and SOPs in the Infusion Suite; Payer Relationship Management; Infusion Referrals</p>
Jim Knepp	Product Director, Site of Care (June 2012–October 2015)	Significantly involved in the SOC strategy and the development of IOI educational materials, including IOI Support Services, in use between June 2012 and October 2015.

<b>Individual</b>	<b>Title</b>	<b>IOI Support Program(s)</b>
		<p>Listed as the Project Owner on relevant PRC forms, including for at least the following IOI Support Services:</p> <p>IV Therapy: An Important Option for Your Patients (a/k/a Why IV?)</p>
Hitu Malhotra	Product Manager, Remicade (Sept. 2010–Apr. 2012)	<p>Significantly involved in the SOC strategy and the development of IOI educational materials, including IOI Support Services, in use between September 2010 and April 2012.</p> <p>Listed as the Project Owner on relevant PRC forms, including for at least the following IOI Support Services:</p> <p>Considerations for Proactive Practice Management; Enhancing Infusion Efficiency; Infusion Optimization Modeler (IOM); Managing Biologics in the Physician Office; Practice Compliance for Remicade; Private Payer Contracting Considerations: Part 2; Successful Implementation of a New Infusion Suite</p>
Thao Marzullo	Product Manager, Site of Care Marketing (July 2013–Aug. 2015)	<p>Significantly involved in the SOC strategy and the development of IOI educational materials, including IOI Support Services, in use between July 2013 and August 2015.</p> <p>Listed as the Project Owner on relevant PRC forms, including for at least the following IOI Support Services:</p> <p>Payer Relationship Management</p>
Randy McGonigal	Senior Director, Site of Care Marketing (Dec. 2002–Jan. 2010)	Significantly involved in the SOC strategy and the development of IOI educational materials, including IOI

<b>Individual</b>	<b>Title</b>	<b>IOI Support Program(s)</b>
		Support Services, in use between December 2002 and January 2010.
Tim Michael	Product Director, Site of Care (May 2016–June 2019)	<p>Significantly involved in the SOC strategy and the development of IOI educational materials in use between May 2016 and June 2019.</p> <p>Listed as the Project Owner on relevant PRC forms, including for at least the following IOI Support Services:</p> <p>Hot Buttons and Practice Pearls - Payer Relationship Management; Hot Buttons and Practice Pearls - Inventory and Supply Management; Hot Buttons and Practice Pearls - In-Office Infusion Drug Procurement Models; Billing and Coding for Infusions; Considerations for Proactive Practice Management</p>
Tom Nyairo	Associate Product Manager, Care Delivery Strategies (Aug. 2004–Nov. 2006)	<p>Significantly involved in the SOC strategy and the development of IOI educational materials, including IOI Support Services, in use between August 2004 and November 2006.</p> <p>Listed as the Project Owner on relevant PRC forms, including for at least the following IOI Support Services:</p> <p>Enhancing Patient Care and Access; Infusion Optimization Modeler (IOM); Infusion Therapy Services Provided in Converted ASC Space; Remicade Account Review</p>
Bill Pillat	Product Manager, Site of Care (May 2017–Aug. 2019)	Significantly involved in the SOC strategy and the development of IOI educational materials, including IOI Support Services, in use between May 2017 and August 2019.

<b>Individual</b>	<b>Title</b>	<b>IOI Support Program(s)</b>
		<p>Listed as the Project Owner on relevant PRC forms, including for at least the following IOI Support Services:</p> <p>Infusion Services Review (iBiz); Quality of Care in the Infusion Suite; In-Office Infusion Drug Procurement Models;</p> <p>Infusion Suite Scheduling &amp; Staffing; Specialty Drug Market Dynamics: Implications for Infusions; Inventory and Supply Management</p>
Faiz Sadeq	Product Manager, Alternative Site of Care (Dec. 2010–July 2011); Product Manager, Site of Care/Hospital (July 2011–Dec. 2012)	<p>Significantly involved in the SOC strategy and the development of IOI educational materials, including IOI Support Services, in use between December 2010 and December 2012.</p> <p>Listed as the Project Owner on relevant PRC forms, including for at least the following IOI Support Services:</p> <p>Checkpoints for Infusion Center Optimization; Managing Biologics in the Physician Office; Private Payer Contracting Considerations</p>
Scott Shelhamer	Regional Business Director (Apr. 2015–Feb. 2020)	Significantly involved in the SOC strategy and the development of IOI educational materials, including IOI Support Services, in use between April 2015 and February 2020.
Sandra Shpilberg	Product Manager (2002–2005)	<p>Significantly involved in the SOC strategy and the development of IOI educational materials in use between</p> <p>Listed as the Project Owner on relevant PRC forms, including for at least the following IOI Support Services:</p> <p>Setting Up In-Office Infusions of Remicade;</p>

<b>Individual</b>	<b>Title</b>	<b>IOI Support Program(s)</b>
		Private Payer Contracting Considerations for Remicade; Remicade Account Review (Physician Office Account Review for Remicade)
David Silver	Product Director, Remicade (Aug. 2008–Aug. 2011)	Listed as the Project Owner on relevant PRC forms, including for at least the following IOI Support Services:  <u>Emerging Trends in Healthcare</u>
Karen Trahan	Regional Business Director (2000–2015)	Significantly involved in the SOC strategy and the development of IOI educational materials, including IOI Support Services, in use between 2000 and 2015.
Michael Wolfe	Product Director, Marketing, Site of Care (Oct. 2010–Apr. 2012); Product Director, Rheumatology Marketing (Apr. 2012–Apr. 2016)	Significantly involved in the SOC strategy and the development of IOI educational materials, including IOI Support Services, in use between October 2010 and April 2016.  Listed as the Project Owner on relevant PRC forms, including for at least the following IOI Support Services:  <u>Managing Biologics in the Physician Office; Successful Implementation of a New Infusion Suite</u>
David Wright	Group Product Director, Stakeholder (Feb. 2013–Dec. 2014); Group Product Director, Rheumatology, IV/IOI (Dec. 2014–Mar. 2016)	Significantly involved in the SOC strategy and the development of IOI educational materials, including IOI Support Services, in use between February 2013 and March 2016.
Michael Ziskind	Director, Public Payer Policy, Strategy & Marketing (Centocor) (1998-2006)	Significantly involved in the SOC strategy and the development of IOI educational materials, including IOI Support Services, in use between 1998 and 2006.  Listed as the Project Owner on relevant PRC forms, including for at least the following IOI Support Services:

<b>Individual</b>	<b>Title</b>	<b>IOI Support Program(s)</b>
		Infusion Therapy Services Provided in ASC; Managing Biologics in the Physician's Office

**TOPIC NO. 2:** The persons (excluding the PRC) that had significant involvement in the decision to stop providing any or all of the IOI Support Services (including the specific IOI Support Service(s) in which each such person had the significant involvement, the approximate date(s) of the significant involvement, the person's last known address and phone number, and, if an individual, the position they held at the time of their significant involvement).

*Relevant time period:* From April 9, 2003 until February 19, 2020.

**RESPONSE TO TOPIC NO. 2:**

Janssen objects to this Topic to the extent that it is overly broad and unduly burdensome and not proportional to the needs of the case, and thus exceeds the scope of discoverable matters under Federal Rule of Civil Procedure 26.

Janssen further objects to this Topic to the extent it is cumulative and seeks information that is duplicative of what is contained in the documents or written discovery that Janssen has already produced.

Janssen further objects that this Topic on the ground that it is vague, ambiguous, and overbroad and does not describe with reasonable particularity the matters on which examination is requested as required by Fed. R. Civ. P. 30(b)(6). For example, Janssen objects to the Topic's use of the term "significant involvement," as that term is not defined. "Significant involvement," in particular, is an inherently subjective term, and reasonable minds could differ as to whether a particular person was "significantly" involved in any given activity. This response is based on Janssen's good faith understanding, and it seeks to address Relator's concerns about providing a response that is over-inclusive or under-inclusive.

Further, pursuant to the Court's March 9, 2023 order, Janssen's response will "only be with regard to the services at issue in this case, not all services." See ECF No. 375 at 18.

Accordingly, Janssen's response to Topic No. 2 will be with respect to the IOI Support Services identified by Relator in response to Janssen's Interrogatory No. 2. *See* Relator's 3d Supplemental Objections and Responses to Janssen's Rog. No. 2 (January 27, 2023).

Subject to and without waiving the foregoing objections, Janssen responds as follows:

As a general matter, the individuals significantly involved in the decision to discontinue particular IOI Support Services were the Product Director and Product Manager responsible for the IOI educational materials used by the ABSs.

The following list encompasses the individuals significantly involved in the decision to discontinue particular IOI Support Services identified by Relator in response to Janssen's Interrogatory No. 2:

<b>Individual</b>	<b>Title</b>	<b>IOI Support Program(s)</b>
John Arena	Product Manager, Site of Care (May 2009–June 2010); Product Director, Site of Care (July 2010–approx. 2012)	Significantly involved in the decision to stop providing any IOI Support Services between May 2009 and 2012.  Programs that were discontinued between May 2009 and 2012 included:  Managing Biologics in the Physician Office; Successful Infusion Site Management for Gastroenterology; Successful Implementation of a New Infusion Suite for Gastroenterology Practices; Successful Implementation of a New Infusion Suite; Private Payer Contracting Considerations – Part 1 and Part 2 (a/k/a Private Payer Contracting Considerations for Therapy With Remicade); Enhancing Efficiency and Capacity; Considerations for Working With a Specialty Pharmacy;

<b>Individual</b>	<b>Title</b>	<b>IOI Support Program(s)</b>
		Becoming an Alternative Site of Care for Therapy with Remicade in Your Community
Janice Babia-Ramos	Manager, Health Economics & Reimbursement (Jan. 2003–Jan. 2005); Senior Manager, Site of Care (Feb. 2005–Mar. 2005); Associate Director, Site of Care (Mar. 2005–May 2005)	Significantly involved in the decision to stop providing any IOI Support Services between January 2003 and May 2005.  Programs that were discontinued between January 2003 and May 2005 included:  Infusion Suite Designer
Michelle Carrigan	Product Director, Channel Marketing (Nov. 2019–Mar. 2022)	Significantly involved in the decision to stop providing any IOI Support Services between November 2019 and February 2020.
Lawrence Conley	Product Manager, Site of Care/Institutional Marketing (Feb. 2013–Oct. 2013); Product Manager, Gastroenterology (Nov. 2013–Apr. 2016)	Significantly involved in the decision to stop providing any IOI Support Services between February 2013 and April 2016.  Programs that were discontinued between January 2013 and April 2016 included:  Checkpoints for Infusion Center Optimization; Efficiency Checklist; Infusion Optimization Modeler (IOM); Setting Up In-Office Infusions of Remicade: Informational Resources
Joseph Donahue	Product Manager, Site of Care (May 2006–June 2007)	Significantly involved in the decision to stop providing any IOI Support Services between May 2006 and June 2007.  Programs that were discontinued between May 2006 and June 2007 included:  Remicade Account Review (a/k/a Physician Office Account Review for Remicade)

<b>Individual</b>	<b>Title</b>	<b>IOI Support Program(s)</b>
Ken Gillmer	Senior Product Manager, Site of Care Marketing (June 2006–Aug. 2007); Associate Director, Site of Care (Aug. 2007–Oct. 2008); Director, Site of Care Marketing (Oct. 2008–Oct. 2010)	<p>Significantly involved in the decision to stop providing any IOI Support Services between June 2006 and October 2010.</p> <p>Programs that were discontinued between June 2006 and October 2010 included:</p> <p>Remicade Account Review (a/k/a Physician Office Account Review for Remicade)</p>
Kendra Heusinkveld	Product Manager, Emerging Stakeholders (Oct. 2015–May 2017)	<p>Significantly involved in the decision to stop providing any IOI Support Services between October 2015 and May 2017.</p> <p>Programs that were discontinued between October 2015 and May 2017 included:</p> <p>Considerations for Proactive Practice Management (a/k/a Current Considerations for Proactive Practice Management; Proactive Practice Management); Considerations for Standard Operating Procedures in the Infusion Suite; Electronic Health Records and Meaningful Use; Electronic Health Records and Meaningful Use 2 (a/k/a EHR/MU2); Payer Relationship Management; Practice Compliance for Remicade</p>
Jim Knepp	Product Director, Site of Care (June 2012–October 2015)	<p>Significantly involved in the decision to stop providing any IOI Support Services between June 2012 and October 2015.</p> <p>Programs that were discontinued between June 2012 and October 2015 included:</p> <p>Checkpoints for Infusion Center Optimization;</p>

<b>Individual</b>	<b>Title</b>	<b>IOI Support Program(s)</b>
		Efficiency Checklist; Infusion Optimization Modeler (IOM); Infusion Therapy Services Provided in Converted ASC Space (a/k/a Infusion Services and Ambulatory Surgical Centers (ASCs) – Planning Considerations; ASC Space Reclassification for Infusion Therapy); Private Payer Contracting Considerations – Part 1 and Part 2 (a/k/a Private Payer Contracting Considerations for Therapy With Remicade); Setting Up In-Office Infusions of Remicade: Informational Resources
Hitu Malhotra	Product Manager, Remicade (Sept. 2010–Apr. 2012)	<p>Significantly involved in the decision to stop providing any IOI Support Services between September 2010 and April 2012.</p> <p>Programs that were discontinued between June September 2010 and April 2012 included:</p> <p>Becoming an Alternative Site of Care for Therapy with Remicade in Your Community; Considerations for Working With a Specialty Pharmacy; Enhancing Efficiency and Capacity; Private Payer Contracting Considerations – Part 1 and Part 2 (a/k/a Private Payer Contracting Considerations for Therapy With Remicade)</p>
Thao Marzullo	Product Manager, Site of Care Marketing (July 2013–Aug. 2015)	<p>Significantly involved in the decision to stop providing any IOI Support Services between July 2013 and August 2015.</p> <p>Programs that were discontinued between June July 2013 and August 2015 included:</p>

<b>Individual</b>	<b>Title</b>	<b>IOI Support Program(s)</b>
		Efficiency Checklist; Infusion Optimization Modeler (IOM); Infusion Therapy Services Provided in Converted ASC Space (a/k/a Infusion Services and Ambulatory Surgical Centers (ASCs) – Planning Considerations; ASC Space Reclassification for Infusion Therapy); Setting Up In-Office Infusions of Remicade: Informational Resources
Randy McGonigal	Senior Director, Site of Care Marketing (Dec. 2002–Jan. 2010)	Significantly involved in the decision to stop providing any IOI Support Services between December 2002 and January 2010.  Programs that were discontinued between June December 2002 and January 2010 included:  Infusion Suite Designer; Remicade Account Review (a/k/a Physician Office Account Review for Remicade)
Tim Michael	Product Director, Site of Care (May 2016– June 2019)	Significantly involved in the decision to stop providing any IOI Support Services between May 2016 and June 2019.  Programs that were discontinued between June May 2016 and June 2019 included:  Billing and Coding for Infusions; Considerations for Proactive Practice Management (a/k/a Current Considerations for Proactive Practice Management; Proactive Practice Management); Electronic Health Records and Meaningful Use; Electronic Health Records and Meaningful Use 2 (a/k/a EHR/MU2); Emerging Trends in Healthcare; Infusion Services Review (iBiz); Infusion Suite Scheduling and Staffing;

<b>Individual</b>	<b>Title</b>	<b>IOI Support Program(s)</b>
		IV Therapy: An Important Option for Your Patients; Payer Relationship Management; Practice Compliance for Remicade; Quality of Care in the Infusion Suite
Tom Nyairo	Associate Product Manager, Care Delivery Strategies (Aug. 2004–Nov. 2006)	Significantly involved in the decision to stop providing any IOI Support Services between August 2004 and November 2006.  Programs that were discontinued between August 2004 and November 2006 included:  <u>Infusion Suite Designer</u>
Bill Pillat	Product Manager, Site of Care (May 2017–Aug. 2019)	Significantly involved in the decision to stop providing any IOI Support Services between May 2017 and August 2019.  Programs that were discontinued between May 2017 and August 2019 included:  Billing and Coding for Infusions; Emerging Trends in Healthcare; Infusion Services Review (iBiz); Infusion Suite Scheduling and Staffing; IV Therapy: An Important Option for Your Patients; Payer Relationship Management; Quality of Care in the Infusion Suite
Faiz Sadeq	Product Manager, Alternative Site of Care (Dec. 2010–July 2011); Product Manager, Site of Care/Hospital (July 2011–Dec. 2012)	Significantly involved in the decision to stop providing any IOI Support Services between December 2010 and December 2012.  Programs that were discontinued between December 2010 and December 2012 included:  Managing Biologics in the Physician Office; Successful Infusion Site Management for Gastroenterology;

<b>Individual</b>	<b>Title</b>	<b>IOI Support Program(s)</b>
		Successful Implementation of a New Infusion Suite for Gastroenterology Practices; Successful Implementation of a New Infusion Suite; Private Payer Contracting Considerations – Part 1 and Part 2 (a/k/a Private Payer Contracting Considerations for Therapy With Remicade); Enhancing Efficiency and Capacity; Considerations for Working With a Specialty Pharmacy; Becoming an Alternative Site of Care for Therapy with Remicade in Your Community
Scott Shelhamer	Regional Business Director (Apr. 2015–Feb. 2020)	Significantly involved in the decision to stop providing any IOI Support Services between April 2015 and February 2020.
Sandra Shpilberg	Product Manager (2002–2005)	Significantly involved in the decision to stop providing any IOI Support Services between 2002 and 2005.  Programs that were discontinued between 2002 and 2005 included:  Infusion Suite Designer
Karen Trahan	Regional Business Director (2000–2015)	Significantly involved in the decision to stop providing any IOI Support Services between 2000 and 2015.
Michael Wolfe	Product Director, Marketing, Site of Care (Oct. 2010–Apr. 2012); Product Director, Rheumatology Marketing (Apr. 2012–Apr. 2016)	Significantly involved in the decision to stop providing any IOI Support Services between October 2010 and April 2016.  Programs that were discontinued between October 2010 and April 2016 included:  Becoming an Alternative Site of Care for Therapy with Remicade in Your Community; Checkpoints for Infusion Center Optimization;

<b>Individual</b>	<b>Title</b>	<b>IOI Support Program(s)</b>
		<p>Considerations for Working With a Specialty Pharmacy; Enhancing Efficiency and Capacity; Infusion Optimization Modeler (IOM); Infusion Therapy Services Provided in Converted ASC Space (a/k/a Infusion Services and Ambulatory Surgical Centers (ASCs) – Planning Considerations; ASC Space Reclassification for Infusion Therapy); Practice Compliance for Remicade; Private Payer Contracting Considerations – Part 1 and Part 2 (a/k/a Private Payer Contracting Considerations for Therapy With Remicade); Setting Up In-Office Infusions of Remicade: Informational Resources; Successful Implementation of a New Infusion Suite; Successful Implementation of a New Infusion Suite for Gastroenterology Practices; Successful Infusion Site Management for Gastroenterology (a/k/a Successful Infusion Suite Management for Gastroenterology)</p>
David Wright	<p>Group Product Director, Stakeholder (Feb. 2013–Dec. 2014); Group Product Director, Rheumatology, IV/IOI (Dec. 2014–Mar. 2016)</p>	<p>Significantly involved in the decision to stop providing any IOI Support Services between February 2013 and March 2016.</p> <p>Programs that were discontinued between February 2013 and March 2016 included:</p> <p>Checkpoints for Infusion Center Optimization; Infusion Optimization Modeler (IOM); Infusion Therapy Services Provided in Converted ASC Space (a/k/a Infusion Services and Ambulatory Surgical Centers (ASCs) – Planning Considerations;</p>

<b>Individual</b>	<b>Title</b>	<b>IOI Support Program(s)</b>
		ASC Space Reclassification for Infusion Therapy); Practice Compliance for Remicade; Setting Up In-Office Infusions of Remicade: Informational Resources
Michael Ziskind	Director, Public Payer Policy, Strategy & Marketing (Centocor) (1998-2006)	Significantly involved in the decision to stop providing any IOI Support Services between 1998 and 2006.  Programs that were discontinued between 1998 and 2006 included:  Infusion Suite Designer

**TOPIC NO. 3:** The persons (excluding employees acting in the capacity of an Area Business Specialist or Regional Business Manager) that had significant involvement in assessing, evaluating, and/or analyzing customer demand for and the value customers derived from any or all of the IOI Support Services (including the specific IOI Support Service(s) in which each such person had the significant involvement, the approximate date(s) of the significant involvement, the person's last known address and phone number, and, if an individual, the position they held at the time of their significant involvement).

*Relevant time period:* From October 28, 2006 to until February 19, 2016.

**RESPONSE TO TOPIC NO. 3:**

Janssen objects to this Topic to the extent that it is overly broad and unduly burdensome and not proportional to the needs of the case, and thus exceeds the scope of discoverable matters under Federal Rule of Civil Procedure 26.

Janssen further objects to this Topic to the extent it is cumulative and seeks information that is duplicative of what is contained in the documents or written discovery that Janssen has already produced.

Janssen further objects that this Topic on the ground that it is vague, ambiguous, and overbroad and does not describe with reasonable particularity the matters on which examination is requested as required by Fed. R. Civ. P. 30(b)(6). For example, Janssen objects to the Topic's use of the terms "significant involvement," "customer demand," and "value," as those are not

defined terms. “Significant involvement,” in particular, is an inherently subjective term, and reasonable minds could differ as to whether a particular person was “significantly” involved in any given activity. This response is based on Janssen’s good faith understanding, and it seeks to address Relator’s concerns about providing a response that is over-inclusive or under-inclusive.

Further, pursuant to the Court’s March 9, 2023 order, Janssen’s response will “only be with regard to the services at issue in this case, not all services.” *See* ECF No. 375 at 18. Accordingly, Janssen’s response to Topic No. 3 will be with respect to the IOI Support Services identified by Relator in response to Janssen’s Interrogatory No. 2. *See* Relator’s 3d Supplemental Objections and Responses to Janssen’s Rog. No. 2 (January 27, 2023).

Subject to and without waiving the foregoing objections, Janssen responds as follows:

The Site of Care team, with input from the ABSs, is responsible for determining the educational materials available for use by the ABSs. *See, e.g.*, JANSSEN BIO-011-00002691; JANSSEN BIO-011-00002730; M. Wolfe Dep. Tr. at 74:16-75:22, 256:21-257:4. The determination as to which educational materials would be delivered by the ABSs was based upon the ABSs continued usage of educational materials (*see* JANSSEN BIO-011-00002691; JANSSEN BIO-011-00002730), redundancy of content across educational materials (*see* JANSSEN BIO-014-00001575), and the educational needs of practices that were infusing Remicade and Simponi ARIA, as identified by ABSs (*see* M. Wolfe Dep. Tr. at 74:16-75:22). The individuals responsible for determining the educational materials available for use by the ABSs are identified in response to Topic 1.

Based on its investigation to date, Janssen is unaware of anyone assessing, evaluating, or analyzing “customer demand for” or the “value customers derived from” the IOI Support Services identified by Relator in response to Interrogatory No. 2.

**TOPIC NO. 4:** The persons (excluding the PRC) that had significant involvement in reviewing, assessing, and/or advising you regarding the legality or illegality of providing any or all of the IOI Support Services (including the specific IOI Support Service(s) in which each such person had the significant involvement, the approximate date(s) of the significant involvement, the person's last known address and phone number, and, if an individual, the position they held at the time of their significant involvement).

Relevant time period: From when the strategy of providing the IOI Support Services was devised until February 19, 2020.

**RESPONSE TO TOPIC NO. 4:**

Janssen objects to this Topic to the extent that it is overly broad and unduly burdensome and not proportional to the needs of the case, and thus exceeds the scope of discoverable matters under Federal Rule of Civil Procedure 26.

Janssen further objects to this Topic to the extent it is cumulative and seeks information that is duplicative of what is contained in the documents or written discovery that Janssen has already produced.

Janssen further objects that this Topic on the ground that it is vague, ambiguous, and overbroad and does not describe with reasonable particularity the matters on which examination is requested as required by Fed. R. Civ. P. 30(b)(6). For example, Janssen objects to the Topic's use of the term "significant involvement," as that is not a defined term. "Significant involvement," in particular, is an inherently subjective term, and reasonable minds could differ as to whether a particular person was "significantly" involved in any given activity. This response is based on Janssen's good faith understanding, and it seeks to address Relator's concerns about providing a response that is over-inclusive or under-inclusive.

Further, pursuant to the Court's March 9, 2023 order, Janssen's response will "only be with regard to the services at issue in this case, not all services." *See* ECF No. 375 at 18. Accordingly, Janssen's response to Topic No. 4 will be with respect to the IOI Support Services

identified by Relator in response to Janssen's Interrogatory No. 2. *See* Relator's 3d

Supplemental Objections and Responses to Janssen's Rog. No. 2 (January 27, 2023).

As previously stated, Janssen has not asserted and does not intend to assert the advice of counsel defense. In answering this Topic, Janssen is not disclosing or intending to imply anything about what legal advice may or may not have been provided. For avoidance of doubt, by providing the requested factual information regarding the identities of the individuals who provided privileged legal advice, Janssen is not asserting the advice of counsel defense and has not waived, and has no intention of waiving, any applicable privilege.

Subject to and without waiving the foregoing objections, Janssen responds as follows:

The following list encompasses the Janssen individuals significantly involved in reviewing, assessing, and/or advising Janssen regarding the legality or illegality of providing the IOI Support Services identified by Relator in response to Janssen's Interrogatory No. 2:

<b>Individual</b>	<b>Title</b>	<b>IOI Support Program</b>
Chris Guiton	Assistant General Counsel (July 2007–Mar. 2019); Senior Director, US State Government Affairs (Mar. 2019–present)	General legal advice regarding SOC educational materials, including IOI Support Services, between July 2007 and March 2019.  Listed as the Legal Reviewer on relevant PRC forms, including for at least the following IOI Support Services:  Infusion Services Review (iBiz); Raising the Infusion Suite Experience (RISE)
Kathleen Hamill	Assistant General Counsel, Centocor Board (Apr. 2000–2011); Assistant General Counsel, Regulatory (2011–present)	General legal advice regarding SOC educational materials, including IOI Support Services, between April 2000 and present.  Listed as the Legal Reviewer on relevant PRC forms, including for at

<b>Individual</b>	<b>Title</b>	<b>IOI Support Program</b>
		<p>least the following IOI Support Services:</p> <p>Checkpoints for Infusion Center Optimization;</p> <p>Managing Biologics in the Physician Office;</p> <p>Private Payer Contracting Considerations;</p> <p>Successful Infusion Suite Management for Gastroenterology</p>
Freddy Jimenez	Assistant General Counsel (Sept. 1999–Jan. 2016)	<p>General legal advice regarding SOC educational materials, including IOI Support Services, between 1999 and 2016.</p> <p>Listed as the Legal Reviewer on relevant PRC forms, including for at least the following IOI Support Services:</p> <p>Becoming an Alternative Site of Care; Considerations for Proactive Practice Management; Emerging Trends in Healthcare; Infusion Optimization Modeler (IOM); Practice Compliance for Remicade; Private Payer Contracting Considerations for Remicade; Remicade Account Review; Setting Up In-Office Infusions of Remicade</p>
Michael McCulley	Assistant General Counsel (Apr. 1982–Dec. 2012)	General legal advice regarding SOC educational materials, including IOI Support Services, between 2000 and 2012.
Diedre Meehan	Assistant General Counsel, Regulatory (Aug. 2007–Dec. 2020)	General legal advice regarding SOC educational materials, including IOI Support Services, between August 2007 and December 2020.
Daryl Todd	Senior Counsel, Regulatory (Apr. 2010–June 2015); Assistant General Counsel, Regulatory (June 2015–present)	General legal advice regarding SOC educational materials, including IOI Support Services, between 2010 and present.

<b>Individual</b>	<b>Title</b>	<b>IOI Support Program</b>
John Vaughan	Senior Counsel (2007–June 2012)	<p>General legal advice regarding SOC educational materials, including IOI Support Services, between 2007 and June 2012.</p> <p>Listed as the Legal Reviewer on relevant PRC forms, including for at least the following IOI Support Services:</p> <p>Emerging Trends in Healthcare; Enhancing Infusion Efficiency; Infusion Optimization Modeler (IOM); Infusion Therapy Services Provided in Converted ASC Space; IV Therapy: An Important Option for Your Patients (a/k/a Why IV?); Managing Biologics in the Physician Office; Private Payer Contracting Considerations; Successful Implementation of a New Infusion Suite; Successful Implementation of a New Infusion Suite for Gastroenterology Practices; Successful Infusion Suite Management for Gastroenterology</p>

Additionally, Janssen also retained outside counsel from Reed Smith, Hogan & Hartson, and Akin Gump.

**TOPIC NO. 5:** The persons who analyzed, reviewed, and/or advised whether you should or should not seek an advisory opinion from OIG concerning any of the IOI Support Services (including the specific IOI Support Service(s) addressed or covered by the analysis/analyses, review(s), or advice each such person performed or provided, the approximate date(s), the person's last known address and phone number, and, if an individual, the position held at the time the analysis/analyses, review(s), or advice was/were performed or provided).

Relevant time period: From when the strategy of providing the IOI Support Services was devised until February 19, 2020.

**RESPONSE TO TOPIC NO. 5:**

Janssen objects to this Topic to the extent that it is overly broad and unduly burdensome and not proportional to the needs of the case, and thus exceeds the scope of discoverable matters under Federal Rule of Civil Procedure 26.

Further, pursuant to the Court's March 9, 2023 order, Janssen's response will "only be with regard to the services at issue in this case, not all services." *See* ECF No. 375 at 18. Accordingly, Janssen's response to Topic No. 5 will be with respect to the IOI Support Services identified by Relator in response to Janssen's Interrogatory No. 2. *See* Relator's 3d Supplemental Objections and Responses to Janssen's Rog. No. 2 (January 27, 2023).

Subject to and without waiving the foregoing objections, Janssen responds as follows:

There are no persons who analyzed, reviewed, and/or advised whether Janssen should or should not seek an advisory opinion from OIG concerning any of the IOI Support Services identified by Relator in response to Janssen's Interrogatory No. 2.

**TOPIC NO. 6:** The persons (excluding the PRC) that had significant involvement in reviewing, assessing, and/or advising you whether providing any or all of the IOI Support Services complied with your compliance policies (including the specific IOI Support Service(s) addressed or covered by the review(s), assessment(s), or advice each such person performed or provided, the approximate date(s) of the significant involvement, the person's last known address and phone number, and, if an individual, the position they held at the time of their significant involvement).

Relevant time period: From when the strategy of providing the IOI Support Services was devised until February 19, 2020.

**RESPONSE TO TOPIC NO. 6:**

Janssen objects to this Topic to the extent that it is overly broad and unduly burdensome and not proportional to the needs of the case, and thus exceeds the scope of discoverable matters under Federal Rule of Civil Procedure 26.

Janssen further objects to this Topic to the extent it is cumulative and seeks information that is duplicative of what is contained in the documents or written discovery that Janssen has already produced.

Further, pursuant to the Court's March 9, 2023 order, Janssen's response will "only be with regard to the services at issue in this case, not all services." *See ECF No. 375 at 18.* Accordingly, Janssen's response to Topic No. 6 will be with respect to the IOI Support Services identified by Relator in response to Janssen's Interrogatory No. 2. *See Relator's 3d Supplemental Objections and Responses to Janssen's Rog. No. 2 (January 27, 2023).*

Janssen further objects that this Topic on the ground that it is vague, ambiguous, and overbroad and does not describe with reasonable particularity the matters on which examination is requested as required by Fed. R. Civ. P. 30(b)(6). For example, Janssen objects to the Topic's use of the term "significant involvement," as that is not a defined term. "Significant involvement," in particular, is an inherently subjective term, and reasonable minds could differ as to whether a particular person was "significantly" involved in any given activity. This response is based on Janssen's good faith understanding, and it seeks to address Relator's concerns about providing a response that is over-inclusive or under-inclusive.

As previously stated, Janssen has not asserted and does not intend to assert the advice of counsel defense. In answering this Topic, Janssen is not disclosing or intending to imply anything about what legal advice may or may not have been provided. For avoidance of doubt, by providing the requested factual information regarding the identities of the individuals who provided privileged legal advice, Janssen is not asserting the advice of counsel defense and has not waived, and has no intention of waiving, any applicable privilege.

Subject to and without waiving the foregoing objections, Janssen responds as follows:

The following list encompasses the individuals significantly involved in reviewing, assessing, and/or advising Janssen whether providing the IOI Support Services identified by Relator in response to Janssen's Interrogatory No. 2 complied with Janssen's compliance policies:

<b>Individual</b>	<b>Title</b>	<b>IOI Support Program</b>
Michele Blades	Health Care Compliance Officer (Mar. 2017–present)	<p>General compliance advice regarding SOC educational materials, including IOI Support Services, between March 2017 and February 2020.</p> <p>Listed as the HCC Reviewer on relevant PRC forms, including for at least the following IOI Support Services:</p> <ul style="list-style-type: none"> <li>Infusion Services Review (iBiz);</li> <li>Inventory and Supply Management;</li> <li>Infusion Practice Management Series - Part 1;</li> <li>Infusion Practice Management Series - Part 2;</li> <li>Billing and Coding for Infusions;</li> <li>Quality of Care in the Infusion Suite;</li> <li>In-Office Drug Procurement Models;</li> <li>Infusion Suite Scheduling and Staffing;</li> <li>ICD-10;</li> <li>Specialty Drug Market Dynamics: Implications for Infusions</li> </ul>
Thomas Cornely	Health Care Compliance Officer, Immunology (Apr. 2013–2016)	<p>General compliance advice regarding SOC educational materials, including IOI Support Services, between 2013 and 2016.</p> <p>Listed as the HCC Reviewer on relevant PRC forms, including for at least the following IOI Support Services:</p> <ul style="list-style-type: none"> <li>Billing and Coding for Infusions;</li> <li>Infusion Services Review (iBiz);</li> </ul>

<b>Individual</b>	<b>Title</b>	<b>IOI Support Program</b>
		Infusion Suite Scheduling and Staffing; Infusion Practice Management Series - Part 1; Infusion Practice Management Series - Part 2; In-Office Drug Procurement Models; Billing and Coding for Infusions; Payer Relationship Management; Inventory and Supply Management; ICD-10
John “Chip” Franz	Health Care Compliance Officer (Oct. 2010–Aug. 2014)	General compliance advice regarding SOC educational materials, including IOI Support Services, between 2010 and 2014.  Listed as the HCC Reviewer on relevant PRC forms, including for at least the following IOI Support Services:  Emerging Trends in Healthcare; Infusion Services Review (iBiz); IV Therapy: An Important Option for Your Patients (a/k/a Why IV?); Raising the Infusion Suite Experience (RISE)
Gina Giordano	Health Care Compliance Officer (June 2009–Oct. 2015)	General compliance advice regarding SOC educational materials, including IOI Support Services, between 2009 and 2015.  Listed as the HCC Reviewer on relevant PRC forms, including for at least the following IOI Support Services:  Considerations for Working with a Specialty Pharmacy
Edmund Greenidge	Director, Health Care Compliance (2005–Oct. 2010)	General compliance advice regarding SOC educational materials, including IOI Support Services, between 2005 and 2010.

<b>Individual</b>	<b>Title</b>	<b>IOI Support Program</b>
		<p>Listed as the HCC Reviewer on relevant PRC forms, including for at least the following IOI Support Services:</p> <p>Becoming an Alternative Site of Care; Enhancing Patient Care and Access; Considerations for Proactive Practice Management; Infusion Therapy Services Provided in Converted ASC Space; Managing Biologics in the Physician Office; Setting Up In-Office Infusions of Remicade</p>
Chris Guiton	Assistant General Counsel (July 2007–Mar. 2019); Senior Director, US State Government Affairs (Mar. 2019–present)	<p>General legal advice regarding SOC educational materials, including IOI Support Services, between July 2007 and March 2019.</p> <p>Listed as the Legal Reviewer on relevant PRC forms, including for at least the following IOI Support Services:</p> <p>Infusion Services Review (iBiz); Raising the Infusion Suite Experience (RISE)</p>
Kathleen Hamill	Assistant General Counsel, Centocor Board (Apr. 2000–2011); Assistant General Counsel, Regulatory (2011–present)	<p>General legal advice regarding SOC educational materials, including IOI Support Services, between April 2000 and present.</p> <p>Listed as the Legal Reviewer on relevant PRC forms, including for at least the following IOI Support Services:</p> <p>Checkpoints for Infusion Center Optimization; Managing Biologics in the Physician Office; Private Payer Contracting Considerations;</p>

<b>Individual</b>	<b>Title</b>	<b>IOI Support Program</b>
Freddy Jimenez	Assistant General Counsel (Sept. 1999–Jan. 2016)	<p>Successful Infusion Suite Management for Gastroenterology</p> <p>General legal advice regarding SOC educational materials, including IOI Support Services, between 1999 and 2016.</p> <p>Listed as the Legal Reviewer on relevant PRC forms, including for at least the following IOI Support Services:</p> <ul style="list-style-type: none"> <li>Becoming an Alternative Site of Care;</li> <li>Considerations for Proactive Practice Management; Emerging Trends in Healthcare;</li> <li>Infusion Optimization Modeler (IOM);</li> <li>Practice Compliance for Remicade;</li> <li>Private Payer Contracting Considerations for Remicade;</li> <li>Remicade Account Review;</li> <li>Setting Up In-Office Infusions of Remicade</li> </ul>
Roger Kung	Health Care Compliance Officer (2011–2012)	<p>General compliance advice regarding SOC educational materials, including IOI Support Services, between 2011 and 2012.</p> <p>Listed as the HCC Reviewer on relevant PRC forms, including for at least the following IOI Support Services:</p> <ul style="list-style-type: none"> <li>Checkpoints for Infusion Center Optimization;</li> <li>Managing Biologics in the Physician Office;</li> <li>Private Payer Contracting Considerations</li> </ul>
Michael McCulley	Assistant General Counsel (Apr. 1982–Dec. 2012)	General legal advice regarding SOC educational materials, including IOI Support Services, between 2000 and 2012.

<b>Individual</b>	<b>Title</b>	<b>IOI Support Program</b>
Diedre Meehan	Assistant General Counsel, Regulatory (Aug. 2007–Dec. 2020)	General legal advice regarding SOC educational materials, including IOI Support Services, between August 2007 and December 2020.
Erin Parsons	Health Care Compliance Officer (Jan. 2015–Nov. 2019)	General compliance advice regarding SOC educational materials, including IOI Support Services, between 2015 and 2019.  Listed as the HCC Reviewer on relevant PRC forms, including for at least the following IOI Support Services:  ICD-10; Specialty Drug Market Dynamics: Implications for Infusions
Maripat Rhood	Manager, Health Care Compliance (May 2001–July 2007)	General compliance advice regarding SOC educational materials, including IOI Support Services, between May 2001 and July 2007.
Michael Schoeck	Director, HCC and Privacy (Oct. 2002–Aug. 2008); Director, HCC (Aug. 2008–Dec. 2010)	General compliance advice regarding SOC educational materials, including IOI Support Services, between 2002 and 2010.  Listed as the HCC Reviewer on relevant PRC forms, including for at least the following IOI Support Services:  Private Payer Contracting Considerations for Remicade; Remicade Account Review
Daryl Todd	Senior Counsel, Regulatory (Apr. 2010–June 2015); Assistant General Counsel, Regulatory (June 2015–present)	General legal advice regarding SOC educational materials, including IOI Support Services, between 2010 and present.
John Vaughan	Senior Counsel (2007–June 2012)	General legal advice regarding SOC educational materials, including IOI Support Services, between 2007 and June 2012.  Listed as the Legal Reviewer on relevant PRC forms, including for at

<b>Individual</b>	<b>Title</b>	<b>IOI Support Program</b>
		<p>least the following IOI Support Services:</p> <p>Emerging Trends in Healthcare; Enhancing Infusion Efficiency; Infusion Optimization Modeler (IOM); Infusion Therapy Services Provided in Converted ASC Space; IV Therapy: An Important Option for Your Patients (a/k/a Why IV?); Managing Biologics in the Physician Office; Private Payer Contracting Considerations; Successful Implementation of a New Infusion Suite; Successful Implementation of a New Infusion Suite for Gastroenterology Practices; Successful Infusion Suite Management for Gastroenterology</p>
Angela Wood	Health Care Compliance Officer (Nov. 2010–June 2014)	<p>General compliance advice regarding SOC educational materials, including IOI Support Services, between 2010 and 2014.</p> <p>Listed as the HCC Reviewer on relevant PRC forms, including for at least the following IOI Support Services:</p> <p>Emerging Trends in Healthcare</p>
Chris Zalesky	Director/Executive Director, Marketing Compliance (Centocor) (April 1998–Oct. 1999); Director, Regulatory Affairs (Janssen) (Oct. 1999–Mar. 2002); Senior Director, Regulatory Affairs (Janssen) (Mar. 2002–May 2004); Executive Director, World Wide Office of Health Care Compliance and Policy (June 2004–Mar. 2010); Vice President, Global Policy & Guidance (2010–2016)	General compliance advice regarding SOC educational materials, including IOI Support Services, between 1998 and 2010.

**TOPIC NO. 7:** The persons that performed the analyses or reviews and/or provided the opinions or advice concerning the HHS or OIG guidance, OIG advisory opinions, Anti-Kickback Statute, False Claims Act, federal regulations, and/or judicial decisions referenced in your responses to interrogatories 15 (amended) and 20-22 that you considered, relied upon, and/or adopted in reaching the asserted belief at the time you were providing the IOI Support Services that you were acting lawfully (including the specific IOI Support Service(s) addressed or covered by the analysis/analyses, review(s), opinion(s), or advice each such person performed or provided, the approximate date(s), the person's last known address and phone number, and, if an individual, the position held at the time the analysis/analyses, review(s), opinion(s), or advice was/were performed or provided).

Relevant time period: From when the strategy of providing the IOI Support Services was devised until February 19, 2020.

**RESPONSE TO TOPIC NO. 7:**

Janssen objects to this Topic to the extent that it is overly broad and unduly burdensome and not proportional to the needs of the case, and thus exceeds the scope of discoverable matters under Federal Rule of Civil Procedure 26.

Janssen further objects to this Topic to the extent it is cumulative and seeks information that is duplicative of what is contained in the documents or written discovery that Janssen has already produced.

Janssen further objects to this Topic to the extent it mischaracterizes Janssen's response to Interrogatory Nos. 15 and 20–22.

Further, pursuant to the Court's March 9, 2023 order, Janssen's response will "only be with regard to the services at issue in this case, not all services." *See* ECF No. 375 at 18. Accordingly, Janssen's response to Topic No. 7 will be with respect to the IOI Support Services identified by Relator in response to Janssen's Interrogatory No. 2. *See* Relator's 3d Supplemental Objections and Responses to Janssen's Rog. No. 2 (January 27, 2023).

As previously stated, Janssen has not asserted and does not intend to assert the advice of counsel defense. In answering this Topic, Janssen is not disclosing or intending to imply anything about what legal advice may or may not have been provided. For avoidance of doubt,

by providing the requested factual information regarding the identities of the individuals who provided privileged legal advice, Janssen is not asserting the advice of counsel defense and has not waived, and has no intention of waiving, any applicable privilege.

Subject to and without waiving the foregoing objections, Janssen responds as follows:

The following list encompasses the individuals significantly involved in the analyses or reviews and/or provided the opinions or advice concerning the legality of the IOI Support Services identified by Relator in response to Janssen's Interrogatory No. 2:

<b>Individual</b>	<b>Title</b>	<b>IOI Support Program</b>
Chris Guiton	Assistant General Counsel (July 2007–Mar. 2019); Senior Director, US State Government Affairs (Mar. 2019–present)	General legal advice regarding SOC educational materials, including IOI Support Services, between July 2007 and March 2019.  Listed as the Legal Reviewer on relevant PRC forms, including for at least the following IOI Support Services:  Infusion Services Review (iBiz); Raising the Infusion Suite Experience (RISE)
Kathleen Hamill	Assistant General Counsel, Centocor Board (Apr. 2000–2011); Assistant General Counsel, Regulatory (2011–present)	General legal advice regarding SOC educational materials, including IOI Support Services, between April 2000 and present.  Listed as the Legal Reviewer on relevant PRC forms, including for at least the following IOI Support Services:  Checkpoints for Infusion Center Optimization; Managing Biologics in the Physician Office; Private Payer Contracting Considerations; Successful Infusion Suite Management for Gastroenterology

<b>Individual</b>	<b>Title</b>	<b>IOI Support Program</b>
Freddy Jimenez	Assistant General Counsel (Sept. 1999–Jan. 2016)	<p>General legal advice regarding SOC educational materials, including IOI Support Services, between 1999 and 2016.</p> <p>Listed as the Legal Reviewer on relevant PRC forms, including for at least the following IOI Support Services:</p> <p>Becoming an Alternative Site of Care; Considerations for Proactive Practice Management; Emerging Trends in Healthcare; Infusion Optimization Modeler (IOM); Practice Compliance for Remicade; Private Payer Contracting Considerations for Remicade; Remicade Account Review; Setting Up In-Office Infusions of Remicade</p>
Mike McCulley	Assistant General Counsel (Apr. 1982–Dec. 2012)	General legal advice regarding SOC educational materials, including IOI Support Services, between 2000 and 2012.
Diedre Meehan	Assistant General Counsel, Regulatory (Aug. 2007–Dec. 2020)	General legal advice regarding SOC educational materials, including IOI Support Services, between August 2007 and December 2020.
Daryl Todd	Senior Counsel, Regulatory (Apr. 2010–June 2015); Assistant General Counsel, Regulatory (June 2015–present)	General legal advice regarding SOC educational materials, including IOI Support Services, between 2010 and present.
John Vaughan	Senior Counsel (2007–June 2012)	<p>General legal advice regarding SOC educational materials, including IOI Support Services, between 2007 and June 2012.</p> <p>Listed as the Legal Reviewer on relevant PRC forms, including for at least the following IOI Support Services:</p> <p>Emerging Trends in Healthcare;</p>

<b>Individual</b>	<b>Title</b>	<b>IOI Support Program</b>
		Enhancing Infusion Efficiency; Infusion Optimization Modeler (IOM); Infusion Therapy Services Provided in Converted ASC Space; IV Therapy: An Important Option for Your Patients (a/k/a Why IV?); Managing Biologics in the Physician Office; Private Payer Contracting Considerations; Successful Implementation of a New Infusion Suite; Successful Implementation of a New Infusion Suite for Gastroenterology Practices; Successful Infusion Suite Management for Gastroenterology

Additionally, Janssen retained outside counsel from Reed Smith, Hogan & Hartson, and Akin Gump.

**TOPIC NO. 8:** The persons that performed the analysis(es) or review(s) and/or provided the opinions or advice concerning the meaning, implication, or significance of the United States' investigation or inquiry referenced in your response to interrogatories 15 (amended) and 20-22 that you considered, relied upon, and/or adopted in reaching the asserted belief at the time you were providing the IOI Support Services that you were acting lawfully (including the specific IOI Support Service(s) addressed or covered by the analysis/analyses, review(s), opinion(s), or advice each such person performed or provided, the approximate date(s), the person's last known address and phone number, and, if an individual, the position held at the time the analysis/analyses, review(s), opinion(s), or advice was/were performed or provided).

Relevant time period: From 2003 until February 19, 2020.

#### **RESPONSE TO TOPIC NO. 8:**

Janssen objects to this Topic to the extent that it is overly broad and unduly burdensome and not proportional to the needs of the case, and thus exceeds the scope of discoverable matters under Federal Rule of Civil Procedure 26.

Janssen further objects to this Topic to the extent it is cumulative and seeks information that is duplicative of what is contained in the documents or written discovery that Janssen has already produced.

Janssen also objects to any implication that the reasonableness of its interpretation of the statutes and regulations at issue in the SAC can only be supported by contemporaneous, affirmative analyses that were performed at a particular time.

Janssen further objects to this Topic to the extent it mischaracterizes Janssen's response to Interrogatory Nos. 15 and 20–22.

As previously stated, Janssen has not asserted and does not intend to assert the advice of counsel defense. In answering this Topic, Janssen is not disclosing or intending to imply anything about what legal advice may or may not have been provided. For avoidance of doubt, by providing the requested factual information regarding the identities of the individuals who provided privileged legal advice, Janssen is not asserting the advice of counsel defense and has not waived, and has no intention of waiving, any applicable privilege.

Subject to and without waiving the foregoing objections, Janssen responds as follows:

The following list encompasses the individuals significantly involved in the United States' investigation referenced in Janssen's response to Relator's Interrogatory Nos. 15 (amended) and 20–22, beginning in 2003:

<b>Individual</b>	<b>Role/Dates</b>
Joseph Braunreuther	General Attorney (Aug. 2001–June 2006); General Counsel, Pharmaceuticals Group (July 2006–Dec. 2008); Associate General Counsel, Litigation (Jan. 2009–Dec. 2011); Deputy General Counsel (Jan. 2012–Dec. 2021)
Freddy Jimenez	Assistant General Counsel (Sept. 1999–Jan. 2016)

Additionally, Janssen retained outside counsel from Reed Smith.

**VERIFICATION**

I am the Vice President, Immunology Portfolio Strategy at Janssen Biotech, Inc. I am authorized to make this verification on behalf of Janssen Biotech, Inc. I have read Defendant's foregoing objections and responses to Plaintiff-Relator Julie Long's 30(b)(6) Deposition Notice served on November 4, 2022. I swear under penalty of perjury that the information provided is true and accurate to the best of my knowledge, information and belief.

Executed on March 23, 2023.

  
\_\_\_\_\_  
Brian Smith

**AS TO OBJECTIONS AND RESPONSES:**

Dated: March 23, 2023

*s/Jason C. Raofield*

---

Jason C. Raofield (BBO No. 641744)  
Ethan M. Posner (*admitted pro hac vice*)  
Kristin M. Cobb (*admitted pro hac vice*)  
Nicholas O. Pastan (*admitted pro hac vice*)  
COVINGTON & BURLING LLP  
One CityCenter, 850 10th Street, NW  
Washington, DC 20001  
(202) 662-6000  
eposner@cov.com  
jraofield@cov.com  
kcobb@cov.com  
npastan@cov.com

*Attorneys for Defendant Janssen Biotech, Inc.*

**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that a true and correct copy of the foregoing document has been served by electronic mail on March 23, 2023, to the following counsel of record:

Theodore J. Leopold  
Leslie M. Kroeger  
Diana L. Martin  
Poorad Razavi  
COHEN MILSTEIN SELLERS & TOLL PLLC  
11780 U.S. Highway One, Suite N500  
Palm Beach Gardens, FL 33408  
[tleopold@cohenmilstein.com](mailto:tleopold@cohenmilstein.com)  
[lkroeger@cohenmilstein.com](mailto:lkroeger@cohenmilstein.com)  
[dmartin@cohenmilstein.com](mailto:dmartin@cohenmilstein.com)  
[prazavi@cohenmilstein.com](mailto:prazavi@cohenmilstein.com)

Casey M. Preston  
Gary L. Azorsky  
Jeanne A. Markey  
COHEN MILSTEIN SELLERS & TOLL PLLC  
100 N. 18<sup>th</sup> Street, Suite 1820  
Philadelphia, PA 19103  
[cpreston@cohenmilstein.com](mailto:cpreston@cohenmilstein.com)  
[gazorsky@cohenmilstein.com](mailto:gazorsky@cohenmilstein.com)  
[jmarkey@cohenmilstein.com](mailto:jmarkey@cohenmilstein.com)

*s/ Kristin M. Cobb*  
Kristin M. Cobb (admitted *pro hac vice*)  
Covington & Burling LLP